K131578

NSK

5. 510(k) SUMMARY

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Mr. Toshihiko Shinozaki Assistant Manager, R&D Dept. Pharmaceutical Affairs Gr. TEL: 0289(64)3380 FAX: 0289(62)6665 t-shinozaki@nsk-nakanishi.co.jp
Date Prepared:	May 28, 2013 *revised August 23, 2013*
Trade Name:	iProphy mobile
Common Name:	Cordless Prophy System
Classification Name:	EKX 872.4200 Handpiece, Direct Drive, AC Powered
Predicate Device:	K110753 Dentsply Midwest RDH Freedom Cordless System
Device Description:	The *iProphy mobile* is a cordless prophylaxis system consisting of an electric motor driven handpiece and an AC powered battery charger (stand). The handpiece utilizes commercially available disposable, single use Disposable Prophy angles (DPA). The handpiece features on-board user controls for power, on/off, and speed with indicators for battery charging, battery life, and speed selection. The *iProphy mobile* is to be used with disposable handpiece sleeves.
Statement of Intended Use (Indications for Use):	The *Nakanishi iProphy mobile* is a cordless prophylaxis handpiece for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing procedures on teeth.
Summary of Technological Characteristics:	Using commercially available disposable Prophy angles (DPA), the *Nakanishi iProphy mobile* can be used to clean and polish teeth. The *iProphy mobile* software driven user controls are located on the cordless handpiece allowing the user to power the device on and off, activate rotation of the device, set the rotation speed, observe the speed setting, observe the battery charging status, and observe the battery status. In addition, the *iProphy mobile* features and auto power-off function after approximately 10 minutes of non-operation, and a last memory function that recalls the most recent settings from when the device was last powered off. Minor differences exist between the *Nakanishi iProphy mobile* and the predicate. The predicate requires the use of a foot pedal while the *iProphy mobile* does not; the predicate requires a higher water exposure rating than the *iProphy mobile*; the predicate utilizes a re-sterilizable sheath while the *iProphy mobile* utilizes disposable handpiece shields like many other dental devices; and the *iProphy mobile* can utilize any commercially available compatible DPA, while the predicate identifies specific compatible DPAs. These minor differences do not impact substantial equivalence of the *Nakanishi iProphy mobile*.

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Performance Testing:	The *iProphy mobile* was developed and is produced under consideration of all applicable technical standards, and internal specifications. Tests were performed which demonstrated that the device is substantially equivalent to the predicate device. Tests included verification/validation testing to internal functional specifications, including software. Documentation was provided demonstrating compliance of the *iProphy mobile* with ISO 10993-1: "Biological evaluation of medical devices -- Part 1: Evaluation and testing" and FDA Guidance "Use on International Standard ISO 10993, "Biological evaluation of medical devices -- Part 1: Evaluation and testing" Documentation was provided demonstrating compliance of the *iProphy mobile* to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards. Testing confirmed that the *iProphy mobile* complies with relevant voluntary safety standards for Electrical safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1 and 60601-1-2. Documentation was provided to demonstrate that the *iProphy mobile* is compliant to ISO 11498: "Dental handpieces: Dental low-voltage electrical motors". Together, these verification/validation activities successfully demonstrated that the *iProphy mobile* correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the *iProphy mobile* device.
Conclusion:	The *iProphy mobile* does not introduce new concerns regarding safety and effectiveness. Therefore, Nakanishi considers the *iProphy mobile* to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in: intended use; principles of operation; functional design; and established medical use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2013

Nakanishi, Incorporated
C/O Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

Re: K131578
Trade/Device Name: iProphy mobile
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: June 14, 2013
Received: June 17, 2013

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K131578

Device Name: *iProphy mobile*

Indications for Use:

The Nakanishi iProphy mobile is a cordless prophylaxis handpiece for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing procedures on teeth.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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